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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,669	03/17/2004	Wei-Wu He	PF140P1D2	4076

22195 7590 07/14/2006

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EXAMINER	
KIM, ALEXANDER D	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/801,669	HE ET AL.	
	Examiner	Art Unit	
	Alexander D. Kim	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. Claims 1-20 are pending in the instant case.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to a isolated polynucleotide encoding SEQ ID NO: 2, a nucleotide homolog, vectors, host cells and a method of making protein and host cells, classified in class 536, subclass 23.5.

II. Claims 1-9, drawn to a isolated polynucleotide encoding SEQ ID NO: 4, a nucleotide homolog, vectors, host cells and a method of making protein and host cells, classified in class 536, subclass 23.5.

III. Claim 10, drawn to a polypeptide of SEQ ID NO: 2 variant, classified in class 435, subclass 195.

IV. Claim 10, drawn to a polypeptide of SEQ ID NO: 4 variant, classified in class 435, subclass 195.

V. Claim 11, drawn to an inhibitor compounds for polypeptide of SEQ ID NO: 2, classified in class 514, subclass 1.

VI. Claim 11, drawn to an inhibitor compounds for polypeptide of SEQ ID NO: 4, classified in class 514, subclass 1.

VII. Claims 12-13, drawn to a method for the treatment using an ICE-LAB-3 polypeptide, classified in class 514, subclass 12.

VIII. Claims 12-13, drawn to a method for the gene therapy treatment by DNA encoding ICE-LAB-3, classified in class 514, subclass 44.

IX. Claims 14-15, drawn to a method for the treatment using an ICE-LAB- 4 polypeptide, classified in class 514, subclass 12.

X. Claims 14-15, drawn to a method for the gene therapy treatment by providing DNA encoding ICE-LAB-4, classified in class 514, subclass 44.

XI. Claims 16, drawn to a method for the treatment of using an ICE-LAB-3 inhibition, classified in class 514, subclass 1.

XII. Claims 17, drawn to a method for the treatment of using an ICE-LAB-4 inhibition, classified in class 514, subclass 1.

XIII. Claim 18 drawn to a diagnostic process by determining a mutation on a nucleic acid sequence encoding polypeptide of SEQ ID NO: 2, classified in class 435, subclass 6.

XIV. Claim 18 drawn to a diagnostic process by determining a mutation on a nucleic acid sequence encoding polypeptide of SEQ ID NO: 4, classified in class 435, subclass 6.

XV. Claim 19, drawn to a diagnostic process by analyzing the presence of the polypeptide SEQ ID NO: 2, classified in class 435, subclass 4.

XVI. Claim 19, drawn to a diagnostic process for a disease by analyzing the presence of the polypeptide SEQ ID NO: 4, classified in class 435, subclass 4.

XVII. Claim 20, drawn to a method for identifying inhibitor compounds for the polypeptide SEQ ID NO: 2, classified in class 435, subclass 7.71.

XVIII. Claim 20, drawn to a method for identifying inhibitor compounds for the polypeptide SEQ ID NO: 4, classified in class 435, subclass 7.71.

3. The inventions are distinct, each from the other because of the following reasons:

Group I and Group II are related by the virtue of polynucleotide encoding polypeptides ICE-LAB. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group I and Group II are mutually exclusive, not obvious variant and have materially different design because the polynucleotide of Group I is distinct from the polynucleotide of Group II because of their distinct structure (different SEQ ID NOs) and chemically distinct sequence. Each polynucleotide requires a separate search against databases. Thus, Group I is patentably distinct from Groups II.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

The following Groups are related inventions and are distinct over the same reason described as in Group I and Group II above.

Group III and Group IV

Group V and Group VI

Group VII and Group VIII

Group IX and Group X

Group XI and Group XII

Group XIII and Group XIV

Group XV and Group XVI

Group XVII and Group XVIII

Group I, III and V are related to each other because a polynucleotide of Group I encodes a protein of Group III that is inhibited by a compound of Group V. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group I, III and V are mutually exclusive and not obvious variants to each other because they are wholly different in structure and function. A nucleic acid's structure is comprised of linear, contiguous nucleotides; a protein's structure comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure

and an inhibitor compound comprised of smaller organic chemical molecules. The nucleic acid's function is to encode a protein while a protein's function is to catalyze a chemical reaction and an inhibitor stops the protein's function. Thus Group I, III and VI have distinct functions from each other as described above.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group I and Group IV, VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group I and Group IV, VI are not capable of use together and have different design because the polynucleotide of Group I encodes a polypeptide of SEQ ID NO: 2 whereas Group IV, VI are products related to polypeptide SEQ ID NO: 4, which has distinct molecule structure of a polypeptide SEQ ID NO: 2.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each

Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group II, IV and VI are related to each other because a polynucleotide of Group II encodes a protein of Group IV that is inhibited by a compound of Group VI. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group II, IV and VI are mutually exclusive and not obvious variants to each other because they are wholly different in structure and function. A nucleic acid's structure is comprised of linear, contiguous nucleotides; a protein's structure comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure and an inhibitor compound comprised of smaller organic chemical molecules. The nucleic acid's function is to encode a protein while a protein's function is to catalyze a chemical reaction and an inhibitor stops the protein's function. Thus Group II, IV and VI have distinct functions from each other as described above.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using

different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group II and Group III, V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group II and Group III, V are not capable of use together and have different design because the polynucleotide of Group II encodes a polypeptide of SEQ ID NO: 4 whereas Group III, V are products related to polypeptide SEQ ID NO: 2, which has distinct molecule structure of a polypeptide SEQ ID NO: 4.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group III and Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group III and Group VI are not capable of use together and have different design because the polypeptide SEQ ID NO: 2 of Group III is a protein catalyzing a specific reaction whereas the inhibitor of Group VI is small organic molecules inhibiting

polypeptide SEQ ID NO: 4, which has distinct molecule structure of a polypeptide SEQ ID NO: 2.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group IV and Group V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group IV and Group V are not capable of use together and have different design because the polypeptide SEQ ID NO: 4 of Group IV is a protein catalyzing a specific reaction whereas the inhibitor of Group V is small organic chemical molecules inhibiting the polypeptide SEQ ID NO: 2, which has distinct molecule structure of a polypeptide SEQ ID NO: 4.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group IV and Group VI are related because the compound of Group VI inhibits the protein of Group IV. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group IV and VI are mutually exclusive, not obvious variants because they are wholly different in structure and function. A inhibitor structure is comprised of small organic molecule while a protein's structure comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure; the compound of Group VI function is to inhibit protein while a protein's function is to catalyze a specific reaction. Also, Group IV cannot be used together with Group VI because they have distinct function as described above.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group I and Group VIII, XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the polynucleotide of Group I can be used as a template in polymerase amplification.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group II and Group X, XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the polynucleotide of Group I can be used as a template in polymerase amplification.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the

other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group III and Group VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the polypeptide of Group III can be used for making protein crystal.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group IV and Group IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the polypeptide of Group IV can be used for making protein crystal.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group III, V and Group XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the protein of Group III and the inhibitor compound of Group V can be used in protein crystallization procedure to make co-crystal.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using

different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group V and Group XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the inhibitor compound can be used in XII-ray crystallization for making co-crystal with ICE-LAP-3.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group VI and Group XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the inhibitor compound can be used in XII-ray crystallization for making co-crystal with ICE-LAP-4.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group IV, VI and Group XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the protein of Group IV and the inhibitor compound of Group VI can be used in protein crystallization procedure to make co-crystal.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the

other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group I, III, V and Group IX-X, XII, XIV, XVI, XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, because methods of Group IX-X, XII, XIV, XVI, XVIII are treatments or diagnosis of disease related to the protein of Group IV encoded by the nucleic acid of Group II, Group I, III, V are not capable of use together with methods of Group IX-X, XII, XIV, XVI, XVIII. Methods of Group IX-X, XII, XIV, XVI are used to treat or diagnose the disease related to the protein of Group IV. Methods of Group XVIII are used to find inhibitors of polypeptide of Group IV. The nucleic acid of Group I encodes the protein of Group III, which is inhibited by the inhibitor of Group V. Thus Group I, III, V and Group IX-X, XII, XIV, XVI, XVIII have different functions as described above.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group II, IV, VI and Group VII-VIII, XI, XIII, XV, XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, because methods of Group VII-VIII, XI, XIII, XV, XVII are treatments or diagnosis of disease related to the protein of Group III encoded by the nucleic acid of Group I, Group II, IV, VI are not capable of use together with methods of Group VII-VIII, XI, XIII, XV, XVII. Methods of Group VII-VIII, XI, XIII, XV are used to treat or diagnose the disease related to the protein of Group IV. A method of Group XVII is used to find inhibitors of polypeptide of Group III. The nucleic acid of Group II encodes the protein of Group IV, which is inhibited by the inhibitor of Group VI. Thus Group I, III, V and Group IX-X, XII, XIV, XVI, XVIII have different functions as described above.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group I and Group VII, XI, XV, XVII are related because methods of Group VII, XI, XIII, XV, XVII are treatment or diagnosis of disease related to the protein encoded by the nucleic acid of Group I. The related inventions are distinct if the inventions as

claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group I and Group VII, XI, XV, XVII are mutually exclusive and not obvious variants because methods of Group VII, XI, XV, XVII do not use the nucleic acid of Group I. Methods of Group VII, XI, XV are used to treat or diagnose the disease related to the protein encoded by a polynucleotide of Group I. The method of Group XVII is used to find inhibitors for a polypeptide of Group I. Thus Group I and Group VII, XI, XV, XVII have different functions as described above.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group II and Group IX, XII, XVI, XVIII are related because methods of Group IX, XII, XVI, XVIII are treatment or diagnosis of disease related to the protein encoded by the nucleic acid of Group II. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect.

See MPEP § 806.05(j). In the instant case, Group II and Group IX, XII, XVI, XVIII are mutually exclusive and not obvious variants because methods of Group IX, XII, XVI, XVIII do not use the polynucleotide of Group II. Methods of Group IX, XII, XVI are used to treat or diagnose the disease related to the protein encoded by the polynucleotide of Group II. The method of Group XVIII is used to find inhibitors for a polypeptide encoded by the Group II. Thus Group II and Group IX, XII, XVI, XVIII have different functions as described above.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group III and Group VIII, XI, XIII, XV are related because methods of Group VIII, XI, XIII, XV are treatment or diagnosis of disease related to the polypeptide of Group III. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group III and Group VIII, XI, XIII, XV are mutually exclusive and not obvious variants because methods of Group VIII, XI, XIII, XV do not use the polypeptide

of Group III. Methods of Group VIII, XI, XIII, XV are used to treat or diagnose the disease related to the protein of Group III, which catalyzes a specific reaction. Thus Group I and Group VIII, XI, XIII, XV have different functions as described above.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group IV and Group X, XII, XIV, XVI are related because methods of Group X, XII, XIV, XVI are treatment or diagnosis of disease related to the polypeptide of Group IV. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group IV and Group X, XII, XIV, XVI are mutually exclusive and not obvious variants because methods of Group X, XII, XIV, XVI do not use the polypeptide of Group IV. Methods of Group X, XII, XIV, XVI are used to treat or diagnose the disease related to the protein of Group IV, which catalyzes a specific reaction. Thus Group IV and Group X, XII, XIV, XVI have different functions as described above.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group V and Group VII-VIII, XIII, XV are related because methods of Group VII-VIII, XIII, XV are treatment or diagnosis of disease related to the polypeptide ICE-LAB-3, which is inhibited by the inhibitor of Group V. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group V and Group VII-VIII, XIII, XV are mutually exclusive and not obvious variants because methods of Group VII-VIII, XIII, XV do not use the inhibitor of Group V. Methods of Group VIII, XIII, XV are used to treat or diagnose the disease related to the ICE-LAB-3, which is inhibited by the Group V. Thus Group V and Group VII-VIII, XIII, XV have different functions as described above.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the

other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group VI and Group IX-X, XIV, XVI are related because methods of Group IX-X, XIV, XVI are treatment or diagnosis of disease related to the polypeptide ICE-LAB-4, which is inhibited by the inhibitor of Group VI. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group VI and Group IX-X, XIV, XVI are mutually exclusive and not obvious variants because methods of Group IX-X, XIV, XVI do not use the inhibitor of Group VI. Methods of Group IX-X, XIV, XVI are used to treat or diagnose the disease related to the ICE-LAB-4 protein, which is inhibited by the Group VI. Thus Group VI and Group IX-X, XIV, XVI have different functions as described above.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group VII-VIII and Group IX-X, XII, XIV, XVI, XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, methods of Group VII-VIII and methods Group IX-X, XII, XIV, XVI, XVIII are not capable of use together and they have different effects because the method of Group VII-VIII requires ICE-LAB-3 polypeptide or a DNA encoding a ICE-LAB-3 polypeptide whereas the method of Group IX-X, XII, XIV, XVI, XVIII requires ICE-LAB-4 polypeptide or a DNA encoding a ICE-LAB-4 polypeptide, which is distinct molecule from ICE-LAB-3.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group VII-VIII, XI, XIII, XV, XVII are related to each other by the virtue of methods related to treatments or a diagnosis of disease related to the polypeptide ICE-LAB-3. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP §

806.05(j). In the instant case, Group VII-VIII, XI, XIII, XV, XVII are mutually exclusive, not obvious variants and have different mode of operation from each other because methods of Group VII-VIII, XI, XIII, XV, XVII have distinct methods step and material requirements from each other thus they cannot be used together.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group IX-X and Group XI, XIII, XV, XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group IX-X and Group XI, XIII, XV, XVII are not capable of use together and they have different effects because the method of Group IX-X requires ICE-LAB-4 polypeptide or a DNA encoding a ICE-LAB-4 polypeptide whereas the method of Group XI, XIII, XV, XVII requires ICE-LAB-3 polypeptide or a DNA encoding a ICE-LAB-3 polypeptide, which is distinct molecule from ICE-LAB-4.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each

Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group IX-X, XII, XIV, XVI, XVIII are related to each other by the virtue of methods related to treatments or a diagnosis of disease related to the polypeptide ICE-LAB-4. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group IX-X, XII, XIV, XVI, XVIII are mutually exclusive, not obvious variants and have different mode of operation from each other because methods of Group IX-X, XII, XIV, XVI, XVIII have distinct method steps and material requirements from each other thus they cannot be used together.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group XI and Group XIV, XVI, XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group XI and Group XIV, XVI, XVIII are not capable of use together and they have different effects because the method of Group XI requires inhibition of ICE-LAB-3 polypeptide whereas the method of Group XIV, XVI, XVIII are related to ICE-LAB-4 polypeptide or a DNA encoding a ICE-LAB-4 polypeptide, which is distinct molecule from ICE-LAB-3.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group XII and Group XIII, XV, XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group XII and Group XIII, XV, XVII are not capable of use together and they have different effects because the method of Group XII requires inhibition of ICE-LAB-4 polypeptide whereas the method of Group XIV, XVI, XVIII are related to ICE-LAB-3 polypeptide or a DNA encoding a ICE-LAB-3 polypeptide, which is distinct molecule from ICE-LAB-4.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group

requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group XIII and Group XVI, XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group XIII and Group XVI, XVIII are not capable of use together and they have different effects because the method of Group XIII requires to find the mutation of ICE-LAB-3 whereas the method of Group XVI, XVIII are related to ICE-LAB-4 polypeptide or an inhibitor of ICE-LAB-4 polypeptide, which is distinct molecule from ICE-LAB-3.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group XIV and Group XV, XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group XIV and Group XV, XVII are not capable of use together and they have different effects because the method of Group XIV requires to find the mutation of ICE-

LAB-4 whereas the method of Group XV, XVII are related to ICE-LAB-3 polypeptide or an inhibitor of ICE-LAB-3 polypeptide, which is distinct molecule from ICE-LAB-4.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group XV and Group XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group XV and Group XVIII are not capable of use together and they have different effects because the method of Group XV is a process of analyzing the presence of the polypeptide ICE-LAB-3 whereas the method of Group XVIII is used to find inhibitor for ICE-LAB-4 polypeptide, which is a distinct molecule from ICE-LAB-3.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group XVI and Group XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group XVI and Group XVII are not capable of use together and they have different effects because the method of Group XVI is a process of analyzing the presence of the polypeptide ICE-LAB-4 whereas the method of Group XVII is used to find inhibitor for ICE-LAB-3 polypeptide, which is a distinct molecule from ICE-LAB-4.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

4. Group XVI and Group XVIII are related. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group XVI and Group XVIII are mutually exclusive, not obvious variants and cannot be used together because each method has distinct steps. The method of Group XVIII requires inhibition of ICE-LAB-4 polypeptide whereas the method of Group XVI is used to

analyze the presence of the ICE-LAB-4. Thus Group XVI and Group XVIII have different functions.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Notice of Possible Rejoinder

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of

35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander D. Kim whose telephone number is (571) 272-5266. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alexander Kim
July 10, 2006

KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER